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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,247	04/02/2007	Reed Gamble	330499.00050	3023
27160 7590 08/18/2009 KATTEN MUCHIN ROSENMAN LLP (C/O PATENT ADMINISTRATOR) 2900 K STREET NW, SUITE 200 WASHINGTON, DC 20007-5118			EXAMINER KARPINSKI, LUKE E	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,247

Applicant(s)

GAMBLE, REED

Examiner

LUKE E. KARPINSKI

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-12, 16-23, 25, 26, 28 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-12, 16-23, 25, 26, 28 and 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/07/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of amendments, arguments, and remarks filed 5/11/2009 is acknowledged.

Change in Examiner

This application will further be examined by Luke Karpinski; contact information can be found at the end of this action.

Claims

Claims 6-9, 13-15, 24, 27, and 29 are canceled.

Claims 32-39 are new.

Claims 1, 10-12, 18, 19, 22, 23, 25, 28, and 30 are amended.

Claims 1-5, 10-12, 16-23, 25, 26, 28, and 30-39 are currently pending and under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Maintained Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 10-12, 18-20, 22, 23, 25, 28, and, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins (US 5,352,457) in view of Edwards et al. (US 6,037,280), Woods (WO 02/059407) and von Trebra et al. (US 5,609,945).

Applicant claims a patch comprising a first layer that is adhesive and a second layer comprising a material adjacent to the first layer, wherein at least one of the first and second layers is opaque to UV radiation.

***Determination of the scope and content of the prior art
(MPEP §2141.01)***

Jenkins teaches in Figure 1, a transdermal device comprising a backing adjacent to an adhesive layer and an adhesive layer. Column 5, lines 32-36 teach examples of materials that can be used as the backing layer such as metallized polyester laminate.

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

Jenkins does not teach the addition of a UV radiation blocking agent or calendering the blocking agent or the shape of the patch being circular. It is for this that

Edwards et al. and Woods are joined. Jenkins does not teach that the patch is substantially transparent to visible light. It is for this that von Trebra et al. is joined.

Edwards teaches the use of UV blocking particles on fabrics for the purpose of deflecting, reflecting, absorbing and/or scattering ultraviolet rays (col. 2, lines 10-15). Column 2, lines 34-51 disclose examples of the UV blocking particles, including metal oxides and its salts.

Woods teaches a method for calendering fabrics for improving the performance of UV blocking agents.

von Trebra et al. teach in examples 1-3, that metallized polyester films prior to coating have a 20% visible light transmission.

Finding of prima facie obviousness
Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Edwards and Woods in the invention of Jenkins to arrive at the claimed invention. As mentioned above, Jenkins teaches the patch as claimed with the addition of the UV blocking agent or calendering the patch. The addition of an UV blocking agent would have been obvious to one of ordinary skill in the art as an additional means of blocking the harmful effects of UV radiation. It would have been within the skill of one in the art after the addition of additional UV protection, to improve the performance. To do so one could look to the teachings of Woods. With respect to the shape of the patch, one of ordinary skill in the art could

design the patch in any manner that would suit the purpose of the patch, which could include the shape of the patch. As mentioned above, Jenkins fail to teach that the patch is substantially transparent to visible light. von Trebra et al. is relied upon to teach that visible light is transmitted through metallized polyester films. It is therefore the position of the examiner that the combinations of references teach the claimed invention and is thus obvious.

Response to Arguments

Applicant's arguments filed 5/11/2009 have been fully considered but they are not persuasive.

Applicant argues that Jenkins only teaches that the backing layer is a metallized polyester film, not the entire transdermal device.

This argument is not found persuasive because applicant makes no claims to the entire device consisting only of a metallized polyester film, applicant also claims an adhesive layer. Jenkins teaches a backing layer and an adhesive layer.

Applicant also argues that layer 4 of Jenkins would be in contact with the skin and therefore the skin would not be visible through the patch.

This argument is not found persuasive because Jenkins teaches that layer 4 may be polyisobutylene, which is a transparent adhesive as evidenced by WO/0123490 to Bonke.

New Objections/Rejections

Claim Objections

Claim 28 is objected to for being dependant on a canceled claim. For the purposes of a compact prosecution the examiner will examine claim 28 as dependant on claim 25.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 10-12, 16-23, 25, 26, 28, and 30-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, breadth of claims, guidance of the specification, the existence of working examples, predictability of the prior art, and the state of the prior art. All of the Wands factors have been considered with regard to the instant claims, with the most relevant discussed below.

1. **Nature of the invention:** The claims are drawn to a patch comprising a transparent adhesive.

2. **Guidance of the Specification:** The specification provides no guidance as to adhesives which may be utilized nor to what type of adhesives may or may not be transparent or translucent.
3. **Working Examples:** The specification provides no working examples with any specific or general types of adhesives to use which may be transparent or translucent.
4. **The quantity of experimentation needed to make or use the invention based on the content of the disclosure:** Due to the fact that the instant specification gives no direction as to the types of, or specific adhesives to utilize, the amount of experimentation for one of ordinary skill to determine which, out of the plethora of known adhesives would be appropriate for contact with human skin and would be, in combination with the backing layer, would be transparent when applied.

Therefore, the guidance from the specification and the lack of working examples provides for undue experimentation to practice the scope of the instant claims. Thus claims 1-5, 10-12, 16-23, 25, 26, 28, and 30-39 are rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 10-12, 16-23, 25, 26, 28, and 30-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's recite a product comprising a first adhesive layer and a second backing layer, said backing layer transparent so that the skin may be seen through the device. It is unclear if said adhesive is also transparent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,241,998 to Muchin.

Muchin discloses a transdermal patch comprising an adhesive layer, a uv agent, and a transparent backing layer (abstract and col. 6, line 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,352,457 to Jenkins in view of US Patent 6,241,998 to Muchin.

Applicant Claims

Applicant claims the patches of claim 1 further comprising, adhesive around the periphery and a protective layer over said adhesive.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Jenkins are delineated above and incorporated herein. In particular Jenkins teaches a protective layer (figure 1).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Jenkins does not teach said adhesive around the periphery as claimed in claim 16. This deficiency in Jenkins is cured by Muchin. Muchin teaches patches wherein said adhesive is not applies to the entire surface (col. 3, lines 40-50).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Regarding claims 16 and 17, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the patch of Jenkins with said adhesive around the periphery as taught by Muchin in order to produce the invention of instant claims 16 and 17.

One of ordinary skill in the art would have been motivated to do this because Jenkins and Muchin both teach patches for adhesion to the skin and Muchin teaches that said patches may have areas without adhesive applied thereto. Therefore it would have been obvious to only apply the adhesive to the outer edge as suggested by Muchin, to the patches of Jenkins.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claim 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,352,457 to Jenkins in view of US Patent 5,167,649 to Zook.

Applicant Claims

Applicant claims the patches of claims 1 and 25 further comprising said second layer as a gel.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Jenkins are delineated above. In particular Jenkins teaches transdermal patches with various materials as backing layers (col. 5).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Jenkins does not teach a gel backing layer as claimed in claims 21 and 26. This deficiency in Jenkins is cured by Zook. Zook teaches patches comprising gel backing layers, which may be waterproof and are perfused with an active agent (abstract, col. 3, line 50, and claim 1).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Regarding claims 21 and 26, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the patch of Jenkins

with a gel backing layer as taught by Zook in order to produce the invention of instant claims 21 and 26.

One of ordinary skill in the art would have been motivated to do this because Jenkins and Zook teach analogous art and Jenkins teaches various backing layer materials. Therefore it would have been obvious to utilize the gel backing of Zook, with the products of Jenkins in order to utilize other known backing layer materials.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claims 1, 4, 5, 11, 12, 16-20, 22, 23, 25, 28, and 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,241,998 to Muchin.

Applicant Claims

Applicant claims are delineated above and incorporated herein.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Muchin teaches dermatological patches comprising an adhesive, a transparent backing layer and a sunscreen (abstract and col. 6, line 1) as claimed in claims 1 and 39.

Muchin further teaches said uv agents on the surface of said backing layer (col. 6, lines 13-14) as pertaining to claim 11, inorganic UV agents (col. 4, lines 39-56), as pertaining to claim 12, said adhesive not applied to entire surface of backing layer (col. 3, lines 45-50), as pertaining to claim 16, a liner, which reads on releasable layer (col. 7, lines 45-67), as pertaining to claim 17, said second layer on said first layer (col. 8, lines 19-20), as pertaining to claim 18, said second layer as a fabric, film, and any material (col. 2, line 60 to col. 3, line 33), as pertaining to claims 19-21, said pads as circular (col. 7, line 27), as claimed in claim 22, manufacture by bringing said layers together (col. 4, lines 27 and 28 and col. 8, lines 18 and 19), as pertaining to claim 25, uv agents (col. 5, lines 39-56 and col. 6 line 1), as pertaining to claim 28.

Ascertainment of the differences between the prior art and the claims

(MPEP 2141.01)

Muchin does not explicitly disclose an example wherein all of the claimed limitations are combined into a single composition. However, Muchin does teach that all of said limitations may be incorporated into a transdermal patch.

Finding of prima facie Obviousness Rational and Motivation

(MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select each component and combine them as instantly claimed because Muchin suggests that the instant components can be combined or mixed together. In a prior art reference it is not necessary for all of the possible compositions to be exemplified in order for the art to render an invention obvious.

Regarding claims 3 and 37, it would have been obvious to utilize any of UVA, UVB, or UVC agents or a combination thereof based on the teaching of the addition of a uv agent to said formulations.

Regarding claims 4, 5, and 31, it is well known in the art that the greater amount of UV agent utilized the higher the SPF or UPF will be and one of skill would have been more than capable to add enough of an agent to achieve a desired SPF such as 40.

Regarding claim 23, the backing layers of Muchin are necessarily waterproof.

Regarding claim 30, said methods were necessarily practices by the application of the patches of Muchin.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claims 2, 3, 33-36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,241,998 to Muchin in view of US Patent Publication 2003/0175328 to Shefer et al.

Applicant Claims

Applicant claims are delineated above and incorporated herein.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Muchin are delineated above and incorporated herein.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Muchin does not teach said second layer opaque to radiation or specific UV agents as claimed in claims 2, 3, 32-36, and 38. This deficiency in Muchin is cured by Shefer et al. Shefer et al. teach transdermal patches comprising sunscreens [0023] [0035], which read on UVA, UVB, and UVC agents and would render said patch as opaque to radiation.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Regarding claims 2, 3, 33-36, and 38, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the

patches of Muchin with the sunscreen agents as taught by Shefer et al. in order to produce the invention of instant claims 2, 3, 33-36, and 38.

One of ordinary skill in the art would have been motivated to do this because both references teach transdermal patches comprising sunscreens and Shefer et al. teach specific sunscreens. Therefore it would have been obvious to utilize the sunscreens of Shefer et al., with the patches of Muchin in order to utilize known sunscreens.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. Claims 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,241,998 to Muchin in view of US Patent 5,167,649 to Zook.

Applicant Claims

Applicant claims are delineated above and incorporated herein.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Muchin are delineated above and incorporated herein. In particular Muchin teaches that any pad material is acceptable (col. 2, lines 60-65).

***Ascertainment of the Difference between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Muchin does not teach a gel pad as claimed in claims 10 and 26. This deficiency in Muchin is cured by Zook. Zook teaches transdermal patches comprising a transparent gel pad (abstract and col. 3, lines 12-51).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Regarding claims 10 and 26, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the patches of Muchin with a gel pad as taught by Zook in order to produce the invention of instant claim 10 and 26.

One of ordinary skill in the art would have been motivated to do this because Muchin teach any pad material is acceptable and Zook teach patches with transparent gel pads. Therefore it would have been obvious to utilize the gel pad of Zook, with the patches of Muchin in order to utilize a known pad material.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,241,998 to Muchin in view of US Patent 6,103,275 to Seitz et al.

Applicant Claims

Applicant claims are delineated above and incorporated herein.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Muchin are delineated above and incorporated herein.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Muchin does not teach said second layer comprising PABA. This deficiency in Muchin is cured by Seitz et al. Seitz et al. teach transdermal patches (col. 3, line 41) comprising sunscreens, specifically PABA (col. 6, lines 15-20).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Regarding claim 32, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the patches of Muchin with PABA as taught by Seitz et al. in order to produce the invention of instant claim 32.

One of ordinary skill in the art would have been motivated to do this because both references teach transdermal patches comprising sunscreens and Seitz et al. teach specific sunscreens, including PABA. Therefore it would have been obvious to utilize the sunscreens of Seitz et al., with the patches of Muchin in order to utilize known sunscreens.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-5, 10-12, 16-23, 25, 26, 28, and 30-39 are rejected.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Mina Haghighatian/
Primary Examiner, Art Unit 1616